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Douglas E. Erickson
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29,530
Reg. No.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application of

Applicant : T. Douglas Mast.
Serial No. : 10/721,034
Filed : November 24, 2003
Title : METHOD FOR MONITORING OF MEDICAL TREATMENT USING
PULSE-ECHO ULTRASOUND
Docket : END5042USCIP
Examiner : Francis J. Jaworski
Art Unit : 3768

Commissioner for Patents
P.O. Box 14350
Alexandria, VA 22313-1450

Sir:

DECLARATION OF FOSTER B. STULEN UNDER 37 CFR 1.132

I, Foster B. Stulen, declare and state the following:

1. For the last 6 years I have been employed by Ethicon Endo-Surgery, Inc., the assignee of the above-identified patent application. I have worked for Ethicon as a Principal Engineer. My technical work over the last 26 years has been concentrated in the field of ultrasound including ultrasound imaging.

2. I received a B.S. degree in Mechanical Engineering from Rensselaer Polytechnic Institute in 1973. I received an SM. degree in Mechanical Engineering in 1975 and a Ph.D. in Mechanical Engineering in 1980 both from Massachusetts Institute of Technology..
3. I have read the above-identified patent application including the claims as amended. I have read the Final Office Action of August 3, 2007 for the above-identified patent application. I have read the Reichenberger (US 5,370,121) patent cited in the Final Office Action of August 3, 2007.
4. The independent claims 1, 13, 16, 25 and 30 require subtracting a second time-varying signal (or imaging signals of a second image frame or of a second set of image frames) from a first time-varying signal (or imaging signals of a first image frame or of a first set of image frames) to derive a time-varying difference signal (or a set of time-varying difference signals). The Reichenberger patent, taken alone or in combination with the Okazaki and/or Lizzi patents, does not teach, suggest or describe this.
5. Two items are key to understanding the difference between the claims and the Reichenberger patent. One is to understand that two time-varying signals from the same location are being subtracted in the claims whereas two signal-amplitude-dependent image pixel values from the same location in two images are being subtracted in the Reichenberger patent. The other is to understand that the term "amplitude" as used in the Reichenberger patent means a number, such as a peak amplitude or an average amplitude, which is time-invariant (fixed) for a particular time-varying signal (but which can change for the next time-varying signal).
6. The Reichenberger patent: determines a first time-invariant amplitude value (such as a maximum amplitude value from a normal or equilibrium value taken as zero or an RMS [root-mean-square] average amplitude value, etc) of the first time-varying signal; then determines a second time-invariant amplitude value of the second time-varying signal; and then subtracts the second time-invariant amplitude value from the first time-invariant amplitude value to derive a time-invariant number (for that particular pair of time-varying signals), wherein the time-invariant number is used to determine a gradation value of a pixel of a location in an image and wherein the pixel gradation value is a fixed value until new signals are received and processed.

The subtraction in the claims yields a time-varying signal whereas the subtraction in the Reichenberger patent yields a fixed (time-invariant) number.

7. Reichenberger discloses ultrasound imaging such as ultrasound B imaging wherein focused ultrasound is transmitted to a first location in the patient, such as a location corresponding to a first pixel location on a corresponding ultrasound B image of the patient. A first ultrasound signal is then received which has been reflected from this first location in the patient. The first ultrasound signal is a time-varying signal and lasts for a finite time. The peak amplitude or an average amplitude of the first ultrasound signal is computed (hereinafter referred to as the first amplitude). A grey-scale value corresponding to the first amplitude will be displayed at the corresponding first pixel location on the corresponding ultrasound B image of the patient. Focused ultrasound is then transmitted to a different second location in the patient, such as a location corresponding to a different second pixel location (such as one adjacent the first pixel location) on the corresponding ultrasound B image of the patient. A second ultrasound signal is then received which has been reflected from this different second location in the patient. The second ultrasound signal is a time-varying signal and lasts for a finite time. The peak amplitude or an average amplitude of the second ultrasound signal is computed (hereinafter referred to as the second amplitude). A grey-scale value corresponding to the second amplitude will be displayed at the corresponding second pixel location on the corresponding ultrasound B image of the patient. The process is repeated until the entire image is completed. Reichenberger subtracts a later-obtained entire image from an earlier-obtained entire image by subtracting the later-obtained first amplitude from the earlier-obtained first amplitude from the same first location in the patient corresponding to the first pixel location, and repeats this for the later and earlier obtained second amplitudes from the same second location (which is different from the first location), etc. to create an image which is the subtraction of the later image from the earlier image.

8. In comparison, taking independent claim 1 as representative of the independent claims, Applicant receives a time-varying first signal of a first ultrasound wave which has been reflected from a location during a first time period. Then, Applicant receives a time-varying second signal of a second ultrasound wave which has been reflected from the same location during a second

time period. Each signal lasts for a finite time or each signal could not be a time-varying signal. Thus, the time-varying difference signal lasts for a finite time. Applicant then generates an indication from the difference signal, the indication showing the effect of the medical treatment in that location of the patient.

9. To illustrate the difference consider the representative waveforms in Figure 1 (which originally was prepared in color). The difference curves are obtained from Gaussian-windowed sinusoids. Waveforms such as these are often used as models of ultrasound pulses. The two large waveforms represent the difference of the magnitudes of the signals (see the large waveform having the "X" markers) and the difference of the signal waveforms (see the large waveform not having the "X" markers). The two small curves are the windowed sinusoids that produced the differences. In order to highlight their different behaviors, the difference curves are scaled by a factor of 10.

10. The difference in magnitudes is essentially the operation in subtracting B mode images that convert magnitude of return to a Brightness (the B in B scan). This is what Reichenberger discloses. The difference in the waveforms is what Mast discloses. These difference curves are constructed from the same windowed sinusoid waveforms, but clearly the results are different. First the peak amplitude of the difference of the means (see the large waveform having the "X" markers") is down nearly 25% of the signal difference (see the large waveform not having the "X" markers). Second positions of the peaks are also different. While the probability is small, the border between two pixels could fall between the peaks. So the apparent spatial shift in the B-scan can be off by a pixel, which represents the spatial resolution. Finally because of the absolute operation in taking magnitudes, the frequency of variation is twice that in the magnitude difference compared to the frequency of the original ultrasound pulse.

11. From working with the signals themselves, one can use correlation of the two difference waveforms to accurately image the positional differences of the two difference waveforms.

12. In summary, the approach disclosed Reichenberger actually has lost information that is contained in the two waveforms as disclosed by MAST. Also the Mast result is achieved over

one individual scan and not the entire B scan image. The information could be used immediately or by the next scan. So the information is obtained much faster too.

13. The subtraction in Reichenberger is derived from the time-invariant amplitude values of a particular before-treatment signal (i.e., a first signal) and a particular during-treatment signal (i.e., a second signal) and is a fixed number and is not a time-varying difference signal. A different fixed number for Reichenberger can be derived by subtracting the time-invariant amplitude values of an additional new third signal and the previous second signal or by subtracting the time-invariant amplitude values of additional new third and fourth signals. However, subtracting fixed amplitude values of third and second signals or fixed amplitude values of third and fourth signals to derive a different fixed number from the fixed number derived by subtracting fixed amplitude values of first and second signals is not subtracting a time-varying second signal from a time-varying first signal to derive a time-varying difference signal.

I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true, and further that these statements and the like so made are punishable by fine or imprisonment or both under Section 101 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the above-identified patent application and any patent issuing thereon.

Date: 9/21/07

Foster B Stulen

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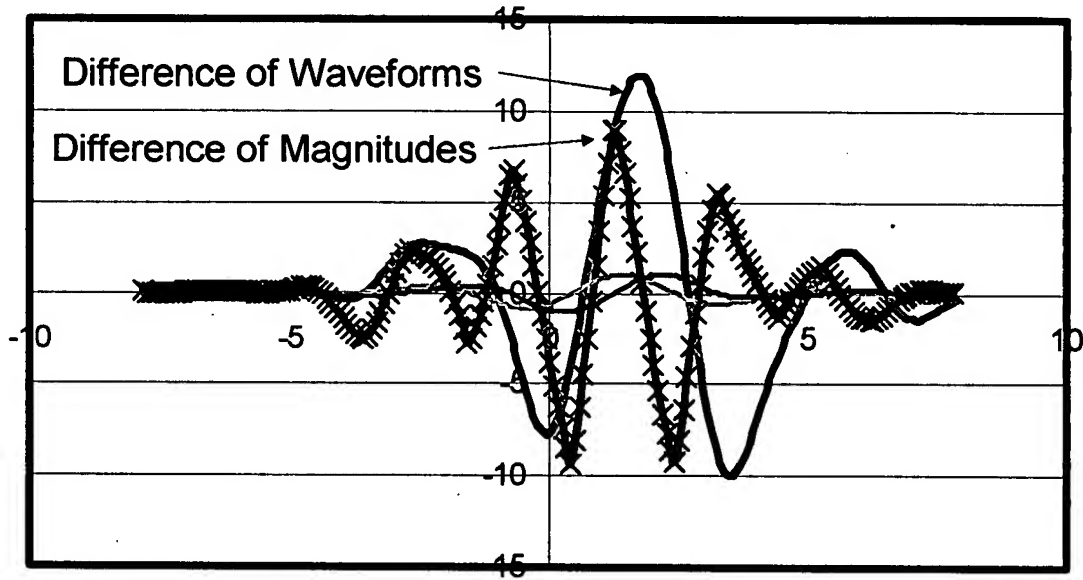


Figure 1. The difference between magnitude differences (red-line with markers) and signal differences (black lines)

9/21/07 Jose B. Stul